



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

ENTERED

June 3, 2004

Mr. Matthew K. Silva, Director
Environmental Evaluation Group
7007 Wyoming Boulevard, N.E.
Suite F-2
Albuquerque, New Mexico 87109



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ENVIRONMENTAL EVALUATION GROUP

Dear Mr. Silva:

On behalf of the U.S. Nuclear Regulatory Commission (NRC), I am writing in response to your letter of April 8, 2004, in which you requested reconsideration of the Commission's decision to remove the packaging requirement for double containment for the shipment of certain forms of plutonium. The Commission removed the double containment requirement in the final rule amending Part 71 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 71), "Compatibility with International Atomic Energy Agency Transportation Safety Standards (TS-R-1) and Other Transportation Safety Amendments" (69 *Federal Register* 3698, January 26, 2004). You requested that the Commission reconsider its decision to remove this requirement because you find no indication that the Commissioners were involved in the amendments to the Federal Register Notice (FRN); and you believe that the NRC response to your comments was inadequate.

I want to assure you that the Commissioners were involved in the changes made to the FRN, prior to publication, to acknowledge and respond to your July 26, 2002 letter. The staff developed responses to your comments and communicated these to the Commission before the final rule was issued (memorandum from William D. Travers, Executive Director for Operations, to the Commission dated January 15, 2004, ADAMS Accession No. ML040140771, Enclosure 1).

With regard to the issues raised in your April 8, 2004 letter, we continue to believe that they were already considered and adequately addressed in the final Part 71 rule, as elaborated in Enclosure 2. In addition, as stated in the letter to you from Martin J. Virgilio, dated March 1, 2004, we believe the changes made in the FRN prior to its publication reference and respond to your July 26, 2002 comments regarding the elimination of the double containment requirement. The March 1, 2004 letter also addressed NRC's consideration of the prepublication copy of EEG-89.

I would like to reiterate a point made in my response to the March 12, 2004 letter from the eight Western Governors. NRC's decision to eliminate the double containment packaging requirement was part of a rulemaking action rather than a packaging certification action. The final NRC rule will permit DOE to consider an alternate Type B package without double containment for the shipments to WIPP. The NRC decision does not invalidate the existing TRUPACT-II design, which still meets all remaining applicable requirements of Part 71. Thus, DOE could continue to use the TRUPACT-II to ship transuranic waste to WIPP. Moreover, DOE cannot change the design of the TRUPACT-II to remove the double containment without demonstrating that it is safe, and only with NRC review and approval of the design change. I would also like to clarify that the double containment criteria do not require

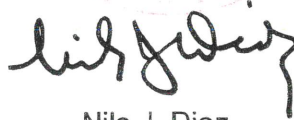
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that each container be independently qualified as a Type B transportation container. For example, the double containment aspect of the TRUPACT-II design is achieved by the use of a thin-walled steel container placed within a thick-walled outer package that together form a single unit evaluated against Part 71. The significance of this is that the inner container itself is not approved as a stand-alone transportation package.

Thank you for your comments and your continued interest in the safe transportation of radioactive material.

Sincerely,

A handwritten signature in black ink, appearing to read "Nils J. Diaz", is written over a faint, circular red stamp that contains the word "DIRECTOR" in blue capital letters.

Nils J. Diaz

Enclosures:

1. Memorandum to the Commission,
dated January 15, 2004
2. Responses to Comments from the
Environmental Evaluation Group,
April 8, 2004

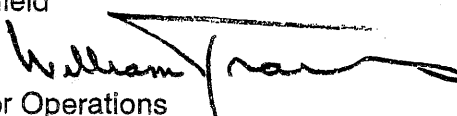


UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

January 15, 2004

MEMORANDUM TO: Chairman Diaz
Commissioner McGaffigan
Commissioner Merrifield

FROM: William D. Travers 
Executive Director for Operations

SUBJECT: CHANGE PAGES FOR 10 CFR PART 71 FINAL RULE
PACKAGE

Due to an administrative error, one commenter letter was not responded to in the preparation of the 10 CFR Part 71 final rule (SECY-03-0141). The commenter brought this to NRC attention on December 17, 2003, upon seeing the SECY paper. Also, during internal processing of the incoming letter, the final rule Federal Register Notice (FRN) was delivered to the Office of Federal Register for publication.

Upon review of the incoming letter, and technical staff review of the comments, the staff determined there were no new or substantive issues raised beyond those made by other commenters. The final rule text would not be altered, but the staff would have clarified some comments/responses in the statement of considerations had we considered the letter earlier. In fact, the same information was provided by the commenter during the collection of comments on Part 71 during the issues report phase of this enhanced public participatory rulemaking (i.e., before the proposed rule was developed).

Due to the length of the FRN, end of year backlog, and the need to publish concurrent to the U.S. Department of Transportation's sister rule, Part 71 has yet to be published. The staff has used this opportunity to provide editorial change pages to the FRN directly to the Federal Register to explicitly address the commenter's issue. Since processing of the DOT and NRC rules is now complete, the changes needed to be provided urgently or the rule recalled.

Attachment: Change Pages

cc: SECY
OGC
OCA
OPA
CFO

CONTACT: Sandra Wastler, NMSS/IMNS
(301) 415-8733

Enclosure 1

Issue 17. Decision on Petition for Rulemaking on Double Containment of Plutonium (PRM-71-12).

Summary of Decision on PRM-71-12. Currently in 10 CFR 71.63(b), plutonium in excess of 0.74 TBq (20 Ci) must be packaged in a separate inner container placed within an outer packaging. This is referred to as double containment. It is the combination of the inner container and the outer packaging that is subjected to the normal conditions of transport (§ 71.71) and the hypothetical accident conditions (§ 71.73). Upon application of the normal conditions of transport and hypothetical accident conditions, the acceptance criteria for shielding, containment, and sub-criticality in § 71.51 must be also met for the total package (inner container and outer packaging), but the containment dispersal acceptance (10^{-6} A₂/hour or 1 A₂/week) are applied to each boundary (i.e., the inner container and the outer packaging). Note however, as a point of clarification, double containment does not mean two Type B containers nested into one.

The final rule grants the petitioner's request to remove the double containment requirement of § 71.63(b). However, the requirement of § 71.63(a) that shipments whose contents contain greater than 0.74 TBq (20 Ci) of plutonium must be made with the contents in solid form is retained. Thus, the petitioner's alternative proposal is denied. This completes action on PRM-71-12.

The NRC has decided to remove the double containment requirement because this regulation is neither risk-informed nor performance-based. There are many nuclides with A₂ values the same or lower than plutonium's for which double containment has never been required. Thus, requiring double containment for plutonium alone is not consistent with the relative hazard rankings in Table A-1. The Type B packaging standards, which the outer containment of plutonium shipments must meet, in and of themselves, provide reasonable assurance that public health and safety and the environment are protected during the

transportation of radioactive material. This position is supported by an excellent safety record in which no fatalities or injuries have been attributed to material transported in a Type B package. The imposition of an additional packaging requirement (in the form of a separate inner container) is fundamentally inconsistent with this position and is technically unnecessary to assure safe transport. Further, removal of this requirement will reduce an unnecessary regulatory burden on licensees, will likely result in reduced risk to radiation workers, and will serve to harmonize Part 71 with TS-R-1.

On the other hand, the imposition of the requirement that plutonium in excess of 0.74 TBq (20 Ci) per package be shipped as a solid does not create a regulatory inconsistency with the Type B package standards. The NRC considers the contents of a package when it is evaluating the adequacy of a packaging's design. The approved content limits and the approved packaging design together define the CoC for a package. However, other than criticality controls and the solid form requirement of § 71.63(a), Subparts E and F do not contain any restrictions on the contents of a package. Thus, while the inner containment requirement in § 71.63(b) can be seen as conflicting with the Type B package standard because the inner containment affects the packaging design, the solid form requirement of § 71.63(a) does not conflict with the packaging requirements of the Type B package standard because the solid form requirement affects only the contents of the package, not the packaging itself.

Affected Sections. Section 71.63.

Discussion of PRM-71-12: The NRC received a petition for rulemaking from International Energy Consultants, Inc. (IEC), dated September 25, 1997. The petition was docketed as PRM-71-12 and was published for public comment (63 FR 8362; February 19, 1998). Based on a request from General Atomic, the comment period was extended to July 31, 1998 (see 63 FR 34335; June 24, 1998). Nine public comments were received on the petition. Four commenters supported the petition, and five commenters opposed the petition.

The petitioner requested that § 71.63(b) be removed. The petitioner argued that the double containment provisions of § 71.63(b) cannot be supported technically or logically. The petitioner stated that based on the "Q-system for the Calculation of A_1 and A_2 Values," an A_2 quantity of any radionuclide has the same potential for damaging the environment and the human species as an A_2 quantity of any other radionuclide.

The NRC believes that the Q-values are based upon radiological exposure hazard models which calculate the allowable quantity limit (the A_1 or A_2 value) necessary to produce a known exposure (i.e., one A_2 of plutonium-239 or one A_2 of cobalt-60 will both yield the same radiation dose under the Q-system models, even though the A_2 values for these nuclides are different (e.g., one A_2 of plutonium-239 = 2×10^{-4} TBq, and one A_2 of cobalt-60 = 1 TBq). The Q-system models take into account the exposure pathways of the various radionuclides, typical chemical forms of the radionuclide, methods for uptake into the body, methods for removal from the body, the type of radiation the radionuclide emits, and the bodily organs the radionuclide preferentially affects. The specific A_1 and A_2 values for each nuclide are developed using radiation dosimetry approaches recommended by the World Health Organization and the ICRP. The models are periodically reviewed by international health physics experts (including representatives from the United States), and the A_1 and A_2 values are updated during the IAEA revision process, based upon the best available data. (Note that changes to the A_1 and A_2 values as a result of changes to the models in TS-R-1 are also discussed in Issue 3 of this rule.) These values are then issued by the IAEA in safety standards such as TS-R-1. When the IAEA has revised the A_1 and A_2 values in previous revisions of its transport regulations, these revised values have been adopted by the NRC and DOT into the transportation regulations in 10 CFR Part 71 and 49 CFR Part 173, respectively.

NRC's review of the current A_1 and A_2 values in Appendix A to Part 71, Table A-1, reveals that 5 radionuclides have an A_2 value lower than plutonium (i.e., plutonium-239), and

11 radionuclides have an A_2 value that is equal to plutonium-239. Because the models used to determine the A_1 and A_2 values all result in the same radiation exposure (i.e., hazard), a smaller A_1 and A_2 value for one radionuclide would indicate a greater potential hazard to humans than a radionuclide with a larger A_1 and A_2 value. Thus, overall, Table A-1 can also be viewed as a relative hazard ranking (for transportation purposes) of the listed radionuclides. In that light, requiring double containment for plutonium alone is not consistent with the relative hazard rankings in Table A-1.

The petitioner also argued that the Type B package requirements should be applied consistently for any radionuclide, whenever a package's contents exceed an A_2 limit. However, Part 71 is not consistent by imposing the double containment requirement for plutonium. The petitioner believes that if Type B package standards are sufficient for a quantity of a particular radionuclide which exceeds the A_2 limit, then Type B package standards should also be sufficient for any other radionuclide which also exceeds the A_2 limit. The petitioner stated that:

While, for the most part, Part 71 regulations embrace this simple logical congruence, the congruence fails under 10 CFR 71.63(b) wherein packages containing plutonium must include a separate inner container for quantities of plutonium having a radioactivity exceeding 20 curies [0.74 TBq] (with certain exceptions).

The petitioner further stated that:

If the NRC allows this failure of congruence to persist, the regulations will be vulnerable to the following challenges: (1) the logical foundation of the adequacy of A_2 values as a proper measure of the potential for damaging the environment and the human species, as set forth under the Q-System, is compromised; (2) the absence of a limit for every other radionuclide which, if exceeded, would require a separate inner container, is an inherently inconsistent safety practice;

and (3) the performance requirements for Type B packages, as called for by 10 CFR Part 71, establish containment conditions under different levels of package trauma. The satisfaction of these Type B package standards should be a matter of proper design work by the package designer and proper evaluation of the design through regulatory review. The imposition of any specific package design feature such as that contained in 10 CFR 71.63(b) is gratuitous. The regulations are not formulated as package design specifications, nor should they be.

The NRC agrees that the Part 71 regulations are not formulated as package design specifications; rather, the Part 71 regulations establish performance standards for a package's design. The NRC reviews the application to evaluate whether the package's design meets the performance requirements of Part 71. Consequently, the NRC can then conclude that the design of the package provides reasonable assurance that public health and safety and the environment are adequately protected.

The petitioner also believes that the continuing presence of § 71.63(b) engenders excessively high costs in the transport of some radioactive materials without a clearly measurable net safety benefit. The petitioner stated that this is so, in part, because the ultimate release limits allowed under Part 71 package performance requirements are identical with or without a "separate inner container," and because the presence of a "separate inner container" promotes additional exposures to radiation through the additional handling required for the "separate inner container." Consequently, the petitioner asserted that the presence or absence of a separate inner container barrier does not affect the standard to which the outer container barrier must perform in protecting public health and safety and the environment. Therefore, the petitioner concluded that given that the outer containment barrier provides an acceptable level of safety, the separate inner container is superfluous and results in unnecessary cost and

radiation exposure. According to the petitioner, these unnecessary costs involve both the design, review, and fabrication of a package, as well as the costs of transporting the package. And the unnecessary radiation exposure involves workers having to handle (i.e., seal, inspect, or move) the "separate inner container."

As an alternative to the primary petition, the petitioner believes that an option to eliminate both § 71.63(a) and (b) should also be considered. Section 71.63(a) requires that plutonium in quantities greater than 0.74 TBq (20 Ci) be shipped in solid form. This option would have the effect of removing § 71.63 entirely. The petitioner believes that the arguments set forth to support the elimination of § 71.63(b) also support the elimination of § 71.63(a). The petitioner did not provide a separate regulatory or cost analysis supporting the request to remove § 71.63(a).

History of the Double Containment Requirement: On June 17, 1974 (39 FR 20960), the AEC issued a final rule which imposed special requirements on the shipment of plutonium. These requirements are located in § 71.63 and apply to shipments of radioactive material containing quantities of plutonium in excess of 0.74 TBq (20 curies). Section 71.63 contains two principal requirements. First, the plutonium contents of the package must be in solid form [§ 71.63(a)]. Second, the packaging containing the plutonium must provide a separate inner containment (i.e., the "double containment" requirement) [§ 71.63(b)]. In addition, the AEC specifically excluded from the double containment requirement of § 71.63(b) plutonium in the form of reactor fuel elements, metal or metal alloys, and other plutonium-bearing solids that the Commission (AEC or NRC) may determine, on a case-by-case basis, do not require double containment. This regulation remained essentially unchanged from 1974 until 1998, when vitrified high-level waste in sealed canisters was added to the list of exempt forms of plutonium in § 71.63(b) (63 FR 32600; June 15, 1998). The double containment requirement is in addition to the existing 10 CFR Part 71 Subparts E and F requirements imposed on Type B packagings

(e.g., the normal conditions of transport and hypothetical accident conditions of §§ 71.71 and 71.73, respectively, and the fissile package requirements of §§ 71.55 and 71.59). Part 71 does not impose a double containment requirement for any radionuclide other than plutonium. Additionally, IAEA standard TS-R-1 does not provide for a double containment requirement (in lieu of the single containment Type B package standards) for any radionuclide.

The AEC issued this regulation at a time when AEC staff anticipated widespread reprocessing of commercial spent fuel, and existing shipments of plutonium were made in the form of liquid plutonium nitrate. Because of physical changes to the plutonium that was expected to be reprocessed (i.e., higher levels of burnup in commercial reactors for spent fuel, which would then be reprocessed), and regulatory concerns with the possibility of package leakage, the AEC issued a regulation that imposed the double containment requirement when the package contained more than 0.74 TBq (20 Ci) of plutonium. This double containment was in addition to the existing Type B package standards on packages intended for the shipment of greater than an A₁ or A₂ quantity of plutonium.

The NRC staff has reviewed the available regulatory history for § 71.63, and has provided a recapitulation of the supporting information which led to the issuance of this regulation. The NRC staff has extracted the following information from several SECY papers the AEC staff submitted to the Commission on this regulation. The NRC staff believes this information is relevant and will provide stakeholders with perspective in understanding the bases for this regulation, and thereby assist stakeholders in evaluating the staff's proposed changes to this regulation.

In SECY-R-702,¹ the AEC staff identified two considerations that were the genesis of the rulemaking that led to § 71.63. AEC staff stated:

¹ SECY-R-702, "Consideration of Form for Shipping Plutonium," June 1, 1973.

First, increasingly larger quantities of plutonium will be recovered from power reactor spent fuel. Second, the specific activity of the plutonium will increase with higher reactor fuel burnup resulting in greater pressure generation potential from plutonium nitrate solutions in shipping containers, greater heat generation, and higher gamma and neutron radiation levels. These changes will make the present nitrate packages obsolete. Thus, from both safety and economic considerations, the transportation of plutonium as [liquid] nitrate will soon require substantial redesign of packages to handle larger quantities as well as to deal with the higher levels of gas evolution (pressurization), heat generation, and gamma and neutron radiation.

There is little doubt that larger plutonium nitrate packages could be designed to meet regulatory standards. The increased potential for human error and the consequences of such error in the shipment of plutonium nitrate are not so easily controlled by regulation. Even though such packages may be adequately designed, their loading and closure requires high operation performance by personnel on a continuing basis. As the number of packages to be shipped increases, the probability of leakage through improperly assembled and closed packages also increases.... More refined or stringent regulatory requirements, such as double containment, would not sufficiently lessen this concern because of the necessary dependence on people to affect engineered.. safeguards.

In SECY-R-74-5,² AEC staff summarized the factors relevant to consideration of a proposed rule following a June 14, 1973, meeting to discuss SECY-R-702, between the

² SECY-R-74-5, "Consideration of Form for Shipping Plutonium," dated July 6, 1973.

Regulatory and General Manager's staffs (i.e., the rulemaking and operational sides of the AEC). The AEC stated:

As a result of this meeting [on June 14, 1973], the [Regulatory and General Manager's] staffs have agreed that the basic factors pertinent to the consideration of form for shipment of plutonium are:

1. The experience with shipping plutonium as an aqueous nitrate solution in packages meeting current regulatory criteria has been satisfactory to date.
2. The changing characteristic of plutonium recovered from power reactors will make the existing packaging obsolete for plutonium nitrate solutions and possibly for solid form. Economic factors will probably dictate considerably larger shipments (and larger packages) than currently used.
3. It is expected that packages can be designed to meet regulatory standards for either aqueous solutions or solid plutonium compounds. Just as in any situation involving the packaging of radioactive materials, a high level of human performance is necessary to assure against leakage caused by human error in packaging. As the number of plutonium shipments increases, as it will, and packages become larger and more complex in design, the probability of such human error increases.
4. The probability of human error with the packaging for liquid, anticipated to be more complex in design, is probably greater than with the packaging for solid. Furthermore, should a human error occur in package preparation or closure, the probability of liquid escaping from the improperly prepared package is greater than for most solids and particularly for solid plutonium materials expected to be shipped.

5. Staff studies reported in SECY-R-62 and SECY-R-509³ conclude that the consequences of release of solid or aqueous solutions do not differ appreciably. Therefore, this paper (SECY-R-702) does not deal with the consequences of releases.
6. It is, therefore, concluded that safety would be enhanced if plutonium were shipped as a solid rather than in solution.

The arguments for requiring a solid form of plutonium for shipment are largely subjective, in that there is no hard evidence on which to base statistical probabilities or to assess quantitatively the incremental increase in safety which is expected. The discussion in the regulatory paper, SECY-R-702, is not intended to be a technical argument which incontrovertibly leads to a conclusion. It is, rather, a presentation of the rationale which has led the Regulatory staff to its conclusion that a possible problem may develop and that the proposed action is a step towards increased assurance against the problem developing. In SECY-R-74-172,⁴ AEC staff submitted a final rule to the Commission for approval.

The proposed rule had contained a requirement that the plutonium be contained in a special form capsule. However, in response to comments from the AEC General Manager, the final rule changed this requirement to a separate inner container (i.e., the double containment requirement). The AEC staff indicated in a response to a public comment in Enclosure B (to SECY-R-74-172) that "[t]he need for the inner containment is based on the desire to provide a substitute for not requiring the plutonium to be in a 'nonrespirable' form."

The regulatory history of § 71.63 indicates that the AEC's decision to require a separate inner container for shipments of plutonium in excess of 0.74 TBq (20 Ci) was based on existing

³ SECY-R-62, "Shipment of Plutonium," and SECY-R-509, "Plutonium Handling and Storage," dated October 16, 1970. These papers concluded that there is no scientific or technical reason to prohibit shipment of plutonium nitrate and recommended that Commission (AEC) efforts be directed toward providing improved safety criteria for shipping containers.

⁴ SECY-R-74-172, "Consideration of Form for Shipping Plutonium," April 18, 1974.

policy and regulatory concerns (i.e., "that a possible problem may develop and that the proposed action [in SECY-R-702] is a step towards increased assurance against the problem developing"). Because of the expectation of a significant increase in the number of liquid plutonium nitrate shipments, the AEC used a defense-in-depth philosophy (i.e., the double containment and solid form requirements), to ensure that respirable plutonium would not be released to the environment during a transportation accident. However, the regulatory history does indicate that the AEC's concerns did not involve the adequacy of existing liquid plutonium nitrate packages. Rather, the AEC's regulatory concern was on the increased possibility of human error combined with an expected increase in the number of shipments that would yield an increased probability of leakage during shipment. The AEC's policy concern was based on an economic decision on whether the AEC should require the reprocessing industry to build new, larger liquid plutonium-nitrate shipping containers, capable of handling higher burnup reactor spent fuel, or to build new, dry, powdered plutonium-dioxide shipping containers. The regulatory history indicates that the AEC staff judged that new, larger, higher burnup-capacity liquid plutonium-nitrate packages could be designed, approved, built, and safely used. However, one of the AEC's principal underlying assumptions for this rule was obviated in 1979 when the Carter administration decided that reprocessing of civilian spent fuel and reuse of plutonium was not desirable. Consequently, the expected plutonium reprocessing economy and widespread shipments of liquid plutonium nitrate within the U.S. never materialized.

On June 15, 1998 (63 FR 32600), in response to a petition for rulemaking submitted by DOE (PRM-71-11) (February 18, 1994; 59 FR 8143), the Commission issued a final rule revising § 71.63(b) to add vitrified high-level waste (HLW) contained in a sealed canister to the list of forms of plutonium exempt from the double containment requirement (June 15, 1998; 63 FR 32600). In its original response to PRM-71-11, NRC proposed in SECY-96-215⁵ to make

⁵ SECY-96-215, "Requirements for Shipping Packages Used to Transport Vitrified Waste Containing Plutonium," dated October 8, 1996.

a "determination" under § 71.63(b)(3) that vitrified HLW contained in a sealed canister did not require double containment. However, the Commission in an SRM on SECY-96-215, dated October 31, 1996, disapproved the staff's approach and directed that resolution of this petition be addressed through rulemaking (the June 15, 1998, final rule was the culmination of this effort). In addition to disapproving the use of a "determination" process, the Commission also directed the staff to "... also address whether the technical basis for 10 CFR 71.63 remains valid, or whether a revision or elimination of portions of 10 CFR 71.63 is needed to provide flexibility for current and future technologies." In SECY-97-218⁶, NRC responded to the SRM's direction and stated "[t]he technical basis remains valid and the provisions provide adequate flexibility for current and future technologies."

Summary of Comments Received on the Petition (PRM-71-12): Nine public comments were received on the petition (petition was published for public comment in 63 FR 8362; February 19, 1998). Four commenters supported the petition, and five commenters opposed the petition. The four commenters supporting the petition essentially stated that the IAEA's Q-system accurately reflects the dangers of radionuclides, including plutonium, and that elimination of § 71.63(a) and (b) would make the regulations more performance based, reduce costs and personnel exposures, and be consistent with the IAEA standards.

The five commenters opposing the petition essentially stated that: (1) Plutonium is very dangerous, especially in liquid form, and therefore additional regulatory requirements are warranted; (2) Existing regulations are not overly burdensome, especially in light of the total expected transportation cost; (3) TRUPACT-II packages meet current § 71.63(b) requirements (TRUPACT-II is a package developed by DOE to transport transuranic wastes (including plutonium) to the Waste Isolation Pilot Plant (WIPP) and has been issued a Part 71 CoC,

⁶ SECY-97-218, "Special Provisions for Transport of Large Quantities of Plutonium (Response to Staff Requirements Memorandum - SECY-96-215)," dated September 29, 1997.

No. 9218); (4) A commenter (the Western Governors' Association) has worked for over 10 years to ensure a safe transportation system for WIPP, including educating the public about the TRUPACT-II package; (5) Any change now would erode public confidence and be detrimental to the entire transportation system for WIPP shipments; and (6) Additional personnel exposure due to double containment is insignificant.

Analysis of Public Comments on the Issues Paper: The NRC has received 48 public comments on this issue in response to the issue paper, in subsequent public meetings, and the workshop (the issues paper was published at 65 FR 44360; July 17, 2000). Industry representatives and some members of the public support the petition. Public interest organizations, Agreement States and State representatives, and the Western Governors' Association, and other members of the public oppose the petition. Several commenters expressed their belief that Congress, in approving the Waste Isolation Pilot Plant Land Withdrawal Act (the Act), Pub. L. 102-579 (106 Stat. 4777), Section 16(a), which mandates that the NRC certify the design of packages used to transport transuranic waste to WIPP, expected those packages to have a double containment. The NRC researched this issue and found that Section 16(a) of the Act does not contain any explicit provisions mandating the use of a double containment in packages transporting transuranic waste to or from WIPP. Section 16(a) of the Act states, in part, "[n]o transuranic waste may be transported by or for the Secretary [of the DOE] to or from WIPP, except in packages the design of which has been certified by the Nuclear Regulatory Commission..." Furthermore, the NRC has reviewed the legislative history⁷ associated with the Act and has not identified any discussions on the use of double

⁷ See Congressional Record Vol. 137, November 5, 1991, pages S15984 - 15997 (Senate approval of S. 1671); Cong. Rec. Vol. 138, July 21, 1992, pages H6301 - 6333 (House approval of H.R. 2637); Cong. Rec. Vol. 138, October 5, 1992, pages H11868 - 11870 (House approval of Conference Report on S. 1671); Cong. Rec. Vol. 138, October 8, 1992 (Senate approval of Conference Report on S. 1671); and Cong. Rec. Vol. 138, October 5, 1992, pages H12221 - 12226 (Conference Report on S. 1671 - H. Rpt. 102-1037).

containment for the shipment of transuranic waste. The legislative history does mention that the design of these packages will be certified by the NRC; however, this language is identical to that contained in the Act itself. Therefore, the NRC believes the absence of specific language in Section 16(a) of the Act requiring double containment should be interpreted as requiring the NRC to apply its independent technical judgment in establishing standards for package designs and in evaluating applications for certification of package designs, to ensure that such packages would provide reasonable assurance that public health and safety and the environment would be adequately protected. In carrying out its mission, the courts have found that the NRC has broad latitude in establishing, maintaining, and revising technical performance criteria necessary to provide reasonable assurance that public health and safety and the environment are adequately protected. An example of these technical performance criteria is the Type B package design standards. Accordingly, the NRC believes that the proposed revision of a technical package standard (i.e., removal of the double containment requirement for plutonium from the Type B package standards) is not restricted by the mandate of Section 16(a) of the Act for the NRC to certify the design of packages intended to transport transuranic material to and from WIPP.

Other commenters stated that stakeholders' expectations were that packages intended to transport transuranic material to and from WIPP would include a double containment provision. Consequently, the commenters expressed a belief that removal of the double containment requirement would decrease public confidence in the NRC's accomplishment of its mission in the approval of the design of packages for the transportation of transuranic waste to and from WIPP. The commenters stated that the public would view elimination of the double containment requirement as a relaxation in safety. The presence of a separate inner container provides defense-in-depth through an additional barrier to the release of plutonium during a transportation accident, according to commenters. In addition, the commenters stated that

plutonium is so inherently deadly, that defense-in-depth is appropriate. The NRC agrees that a double containment does provide an additional barrier. However, the NRC believes that, for the reasons discussed below, double containment is unnecessary to protect public health and safety. The NRC and AEC have not required an additional containment barrier for Type B packages transporting any radionuclides other than plutonium and, before 1974, the AEC did not require double containment for plutonium.

In response to some of the comments opposed to the petition, the NRC believes that removal of § 71.63(b) would not invalidate the design of existing packages intended for the shipment of plutonium. These packages could continue to be used with a separate inner container. The NRC agrees with the commenters that a quantitative cost analysis was not provided by the petitioner.

The NRC has issued Part 71 CoC No. 9218 to DOE for the TRUPACT-II package (Docket No. 71-9218), for the transportation of transuranic waste (including plutonium) to and from the WIPP. The TRUPACT-II package complies with the current § 71.63(b) requirements and has a separate inner container. The TRUPACT-II SAR indicates that the weight of the inner container and its lid is approximately 2,620 lbs. Hypothetically, elimination of the separate inner container would increase the available payload for the TRUPACT-II package from the current 7,265 to 9,885 lbs. Thus, removal of the double containment requirement would potentially increase the TRUPACT-II's available payload by 36 percent. Further, the removal of the inner container from the TRUPACT-II would also potentially increase the available volume. The NRC believes that the ~~proposed~~ **final** rule would not invalidate the existing TRUPACT-II design (i.e., it would still meet all remaining applicable requirements of Part 71). Thus, DOE could continue to use the TRUPACT-II to ship transuranic waste to and from WIPP, or DOE could consider an alternate Type B package.

Additionally, based on comments received in the public meetings, the NRC believes that a misperception exists with respect to TRUPACT-II shipments; removal of the § 71.63(b) double containment requirement would not result in loose plutonium waste being placed inside a TRUPACT-II package. Based upon information contained in the SAR, plutonium wastes (i.e., used gloves, anti-Cs, rags, etc.) are placed in plastic bags, and these bags are sealed inside lined 55-gallon steel drums. Plutonium residues are placed inside cans which are then sealed inside a pipe overpack (a 6-inch or 12-inch stainless steel cylinder with a bolted lid), and the pipe overpack is then sealed inside a lined 55-gallon steel drum. The 55-gallon drums are then sealed inside the TRUPACT-II inner containment vessel, and finally the inner containment vessel is sealed inside the TRUPACT-II package. Consequently, the TRUPACT-II shipping practices employ multiple barriers and would continue to do so. Removal of the inner containment vessel would not be expected to produce a significant incremental increase in the possibility of leakage during normal transportation. The NRC notes that some NRC regulations have established additional requirements for plutonium (e.g., the special nuclear material license application provisions of § 70.22(f)).

The NRC believes that the Type B packaging standards, in and of themselves, provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of radioactive material. This belief is supported by an excellent safety record in which no fatalities or injuries have been attributed to material transported in a Type B package. Type B packaging standards have been in existence for approximately 40 years and have been incorporated into the Part 71 regulations by both the NRC and its predecessor, the AEC. The NRC's Type B package standards are based on IAEA's Type B package standards. Moreover, IAEA's Type B package standards have never required a separate inner container for packages intended to transport plutonium, nor for any other radionuclide.

Therefore, the NRC believes that imposition of an additional packaging requirement (in the form of a separate inner container) is fundamentally inconsistent with the position that Type B packaging standards, in and of themselves, provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of (any type of) radioactive material. Thus, the NRC believes that maintaining § 71.63(b) is not consistent with the other existing Type B packaging standards contained in Part 71.

The NRC also believes that the regulatory history of § 71.63 demonstrates that the AEC's decision to add this section was based on policy and regulatory concerns. However, the NRC also agrees that the use of a double containment does provide defense-in-depth and does decrease the absolute risk of the release of respirable plutonium to the environment during a transportation accident. Consequently, while the defense-in-depth afforded by a double containment does reduce risk, the NRC believes the question which should be focused on is whether the double containment requirement is risk-informed. The NRC is unaware of any risk studies that would provide ~~either a qualitative or~~ quantitative indication of the risk reduction associated with the use of **an NRC-certified double containment packaging** in transportation of plutonium. Rather, the NRC would look to the demonstrated performance record of existing Type B package standards to conclude that double containment is not necessary.

In summary, the AEC indicated (in SECY-R-702 and SECY-R-74-5) that liquid plutonium nitrate packages were safe, and new, larger packages to handle higher burnup reactor spent fuel could also be designed. NRC believes that the AEC's assumption for initiating this requirement was that large scale reprocessing of civilian reactor spent fuel and reuse of plutonium would occur. The decision of former President Carter's administration to forgo the reprocessing of civilian reactor spent fuel and reuse of plutonium obviated the AEC's assumption. Consequently, the AEC's supposition that a human error occurring while sealing a package of liquid plutonium nitrate was more likely to occur with the expected increase in

shipments of plutonium nitrate was also obviated by the Government's decision to forgo the reprocessing of civilian reactor spent fuel. In SECY-97-218, NRC staff indicated that the separate inner container provided an additional barrier to the release of plutonium in an accident. NRC continues to believe that a separate inner container provides an additional barrier to the release of plutonium in an accident, just as a package with triple containment would provide an even greater barrier to the release of plutonium in an accident. However, this type of approach is neither risk informed nor performance based. Consequently, based upon review of the petition, comments on the petition, and research into the regulatory history of the double containment requirement, the NRC agrees that a separate inner container is not necessary for Type B packages containing solid plutonium. NRC believes that the worldwide performance record over 40 years of Type B packages demonstrates that a single containment barrier is adequate. Therefore, the NRC agrees with the petitioner and believes that § 71.63(b) is not technically necessary to provide a reasonable assurance that public health and safety and the environment will be adequately protected during the transportation of plutonium.

While the NRC believes a case can be made for elimination of the separate inner container requirement in § 71.63(b), elimination of the solid form requirement in § 71.63(a) is not as clear. While the same arguments can be made on the obviation of the AEC's basis for originally issuing § 71.63(a) (i.e., the elimination of reprocessing of plutonium), the same regulatory inconsistency between Type B package standards and the inner containment requirement does not exist for the liquid versus solid form argument. The NRC considers the contents of a package when it is evaluating the adequacy of a packaging's design. The approved content limits and the approved packaging design together define the CoC for a package. However, other than criticality controls and the liquid form requirement of § 71.63(a), 10 CFR Part 71 Subparts E and F do not contain any restrictions on the contents of a package. Thus, while the inner containment requirement in § 71.63(b) can be seen as conflicting with the

Type B package standard because the inner containment affects the packaging's design, the solid form requirement of § 71.63(a) does not conflict with the packaging requirements of the Type B package standard because the solid form requirement affects only the contents of the package, not the packaging itself.

The NRC expects that cost and dose savings would accrue from the removal of § 71.63(b). However, because no shipments of liquid plutonium nitrate are contemplated in the U.S., NRC would not expect cost or dose savings to accrue from the removal of § 71.63(a), if that section were to be also removed. Further, the AEC's original bases have been obviated by former President Carter's administration's decision to not pursue a commercial fuel cycle involving the reprocessing of plutonium.

After weighing this information, the NRC continues to believe that the Type B package standards, when evaluated against 40 years of use worldwide, and millions of safe shipments of Type B packages, together provide reasonable assurance that public health and safety and the environment would be adequately protected during the transportation of radioactive material. The NRC believes that, in this case, the reasonable assurance standard, provided by the Type B package requirements, provides an adequate basis for the public's confidence in the NRC's actions.

Analysis of Public Comments on the Proposed Rule.

A review of the comments and the NRC staff's responses for this issue follows:

Comment. ~~Four~~ **Several** commenters suggested that all radioactive materials should require double packaging. Two of these commenters stated double containment is a security and safety precaution. A third stated that existing container requirements are the minimum standards necessary for safety, security, and public acceptance. Another commenter simply objected to the removal of the requirement for double containment of plutonium.

Response. The NRC disagrees with these comments. The NRC has made a finding that single containment of radioactive material provides an adequate level of safety for all radioactive materials. The A₁ and A₂ value summary found at 67 FR 21422; April 30, 2002, under the heading Issue 3, provides information that supports the NRC's basis for this decision. The comments provided no justification for the double containment requirement for shipment of all nuclear materials.

Comment. Several commenters were concerned with NRC's proposal to eliminate double containment. The first of these commenters asked if there is any basis to eliminate the double containment requirement other than to harmonize our rules with the IAEA regulations. The second commenter expressed concern that the "only benefits from eliminating double containment . . . would accrue to the DOE, to contractors, licensees, and shippers in the form of cost savings." Furthermore, the commenter stated that the cost of maintaining transportation safety standards should be borne by those in the industry and that costs should not be "used as an excuse for deregulation or exemptions." A similar argument was made by another commenter who urged NRC not to remove § 71.63(b) reasoning that, as noted in the proposed rulemaking, the petitioner did not provide a quantitative cost analysis; therefore, the contention that "presence of § 71.63(b) engenders excessively high costs" is unsubstantiated. **Another commenter stated that while an 8-13% volume reduction due to weight restrictions caused by double containment is not trivial, the benefits from reducing this weight penalty needs to be balanced against the resulting increase in radiation doses, the increased likelihood of a release in the event of a severe accident, and the increased cost of certifying a new package.**

Response. The primary reason for removing the double containment requirement is that the NRC has no technical justification or basis for maintaining double containment for plutonium or any other radionuclide. The NRC believes the arguments for removing double

containment have been adequately addressed earlier **in this notice and in** the proposed rule under this issue.

While NRC acknowledges that there may be monetary benefits associated with removing double containment, there are other reasons as well, including reduction in personnel exposure for those individuals involved in loading packages for transport. **Further, while double containment does provide an additional barrier against release, the NRC believes that, for reasons previously explained, double containment is unnecessary to protect public health and safety. ~~The last commenter's statements regarding increases in release in the event of a severe accident are addressed elsewhere in other comment/responses for this issue.~~** Moreover, NRC has been and remains committed to providing regulations that are not only risk informed, but also reduce unnecessary regulatory burden.

Comment. One commenter stated that removing the double containment requirement would reduce costs of packaging and associated hardware. The commenter asserted that double containment increases costs without measurable benefit. The commenter then provided cost information and discussed the design, certification, and fabrication of future packaging (e.g., TRUPACT III or the DPP-1 and DPP-2) needed to complete DOE's Accelerated Cleanup strategy for resolution of the legacy wastes and materials from the Cold War.

Response. NRC acknowledges the comment.

Comment. Many commenters opposed the elimination of the double containment requirement because of possible public health and safety consequences.

Response. The commenters provided no basis for their assertions that removing the double-containment requirement would increase public exposure risks. The NRC staff believes that the current Type B package requirements, as applied to all radionuclides, are adequate to protect public health and safety.

Comment. One commenter stated that the principal benefit of removing the double containment requirement would be a reduction in exposure to the workers. The commenter added that it would also result in lower costs.

Response. NRC acknowledges the comment.

Comment. One commenter expressed concern that the A_1 and A_2 values have been used as a justification for single-shell containers for plutonium.

Response: The NRC does not agree with this unsubstantiated statement that the A_1 and A_2 values have been used as justification for the elimination of the double containment requirement for plutonium. The justifications for elimination of the double containment requirement were detailed in the proposed rule on April 30, 2002 (67 FR 21421 through 21425), and focus more on the fact that the original AEC requirement for double containment of plutonium was based on existing policy and regulatory concerns and was not risk informed. While the A_1 and A_2 values are referenced in the discussion, they are referenced from the standpoint that there are other radionuclides with the same or lower A_1 and A_2 values than plutonium. Because these radionuclides have never required double containment, it cannot be argued from a risk standpoint that the shipment of plutonium should be treated any differently.

Comment. Three commenters expressed support for the proposed removal of the requirement for "double containment" of plutonium from § 71.63. One commenter asserted that a single containment barrier is adequate for Type B packages containing more than 20 curies of solid form plutonium. The commenter further stated that the former AEC's rationale for requiring the double containment provision is now moot because the expectation for liquid plutonium nitrate shipments has never materialized. The commenter also expressed opposition to the double containment requirement because it presents continuing costs without commensurate benefits. The commenter stated that removing the double containment requirement would result in a small and acceptable increase in public risk. Furthermore, the

requirement removes flexibility in package designs that might be needed to meet DOE's mission.

Another commenter expressed concern that the double containment requirement was implemented in the 1970s without adequate justification.

The third commenter said that using double containment causes unnecessary worker radiation exposure. This commenter said this unnecessary worker radiation is estimated to be 1200 to 1700 person-rem over a 10-year period. The commenter also said the conditions that justified double containment during the early 1970s have disappeared. These include large numbers of shipments of nitrate solutions or other forms from reprocessing, compounded by crude containment requirements, and the absence of quality assurance requirements. This position was justified because France, Germany, and the United Kingdom, as well as other IAEA Member Nations, no longer require double containment for plutonium. The commenter believed that harmonization of Part 71 with IAEA TS-R-1 was an important goal of this rulemaking because to do so would allow for consistent regulation among the principal nations shipping nuclear materials. Furthermore, it was recommended that NRC eliminate the special requirements for plutonium shipments in § 71.63 for consistency with the use of prescriptive, performance-based safety standards.

Response. The comments are generally in line with statements in the proposed rule on April 30, 2002 (67 FR 21421 through 21425) that described the NRC's bases for elimination of the double containment requirement.

Comment. ~~Four~~ **Several** commenters stated that double containment provides more protection to the public than single containment. One of these commenters stated the belief that the commenter and a majority of the Western Governors are concerned with the proposal to eliminate the double containment requirement for plutonium shipments. The commenter stated that "the regulatory analysis is defective in its failure to recognize likely impacts on the

agreement among the Western Governors' Association, the individual Western States, and DOE for a system of extra regulatory transportation safeguards, which we believe are at the heart of both government and public acceptance of the WIPP transportation program." **One commenter stated that if Section 71.63(b) is deleted, there will very likely be some use of single-contained packages for future WIPP shipments.**

Response. With respect to the last commenter's statement, the use of single containment packages for future shipments is one possible outcome of the change. NRC acknowledges that agreements between DOE and States may be impacted by the elimination of the double containment regulatory requirement. However, any change to NRC regulations that impact how DOE conducts its transportation operations is a DOE decision. As such, DOE and the States ~~will~~ **may need to** negotiate and resolve issues related to DOE's operations.

Comment. One commenter stated that the proposed rule is not risk informed and does not use a common sense approach. Another commenter stated strong agreement with this first commenter. **Another commenter recommended that both 71.63(a) and 71.63(b) be retained but that the limit be expressed as 0.74 TBq (20 Ci) for the total of all actinides with A_2 values equal to or less than 1.0×10^{-3} TBq (2.7×10^{-2} Ci).**

Response. The NRC believes the decision to eliminate double containment is risk informed and reduces an unnecessary regulatory burden. In this context, there is adequate actual operating experience with Type B package shipments to support the Commission's decision to remove the double containment requirement for plutonium packages. There are many nuclides with A_2 values the same or lower than plutonium's that have never required double containment.

Further, current NRC regulations state that, in certain circumstances, plutonium in excess of 0.74 TBq (20 Ci) can be shipped as a normal form solid without requiring double

containment. The shipment of reactor fuel elements containing plutonium is one example. Using the most conservative A_2 value of 0.00541 Ci, 0.74 TBq (20 Ci) of plutonium (Pu-238, Pu-239, Pu-240) equates to an A_2 multiple of roughly 3700. In contrast, using 19 risk-significant nuclides (**including Am-241**) from a typical single boiling water reactor spent fuel assembly (reference NUREG/CR-6672, "Reexamination of Spent Fuel Shipment Risk Estimates," page 7-17), one can calculate a curie content of 148,346 Ci with a cumulative A_2 multiple of just under 790,000 (the assembly also would contain an A_2 multiple of 455,000 of plutonium nuclides). If the A_2 multiple is viewed as a measure of potential health effect, then from a risk-informed standpoint, the shipment of one particular nuclide in a Type B package should not be treated differently from any other nuclide of comparable A_2 in a Type B package. It should be noted that for domestic shipments, there is a well established and excellent safety record associated with the shipment of spent fuel assemblies in single containment spent fuel packages.

Comment. Two commenters stated that removing the double containment requirement would provide health benefits for radiation workers. One commenter argued that the cost of reducing the exposure to workers to the required 1 mrem/yr would be very high. One commenter asserted that we need to balance public safety and the safety of radiation workers.

Response. As discussed in the draft EA, NRC agrees that the removal of the double containment requirement would result in reduced risk to radiation workers.

Comment. One commenter stated that worker exposure estimates are not supported by data. **Another commenter stated that the conclusion that single containment will decrease radiation doses is incorrect for WIPP shipments. The commenter contends that radiation doses would increase to both workers and the general public.**

Response. The **first** commenter's remark about lack of data on worker exposure estimates was true at the time of the public meeting on June 24, 2002, where the comment was made. However, during the comment period, DOE, one of the major entities affected by the

current double containment rule, submitted the results of a detailed study they performed to evaluate the impacts for elimination of the current requirement. In that study, they presented quantifiable data that indicates that over a 10-year period, they could expect to see a reduction of 1200 to 1700 person-rem if the double containment provision is eliminated. **The second commenter provided qualitative and quantitative information (some of which concerned a non-NRC certified cask) that states comes to a contrary conclusion.** While the NRC does not endorse or dispute ~~the either study's conclusions, the results are in line with the NRC's contention that elimination of the double containment requirement will likely result in a reduction in worker radiation exposure~~ **the NRC believes worker dose would be reduced due to less handling. Further, Whether worker or public dose increases or decreases under the rule change,** radiation protection of transport workers (e.g., drivers, inspectors) and the public is provided through the package maximum radiation levels set forth in DOT regulations, which are not a function of double containment.

Comment. One commenter stated that the NRC has not fully evaluated the regulatory impact of the proposed change on the use of the TRUPACT II design.

Response. During the development of the proposed rule, NRC staff used all available data to evaluate the costs and benefits of the proposed change. NRC staff requested specific information on costs and benefits as part of the proposed rule, and the information received was considered during the development of a final position. NRC received a study from the commenter and, while the NRC does not endorse or dispute the study's conclusions, the results are in line with the NRC's contention that elimination of the double containment requirement will likely result in a reduction in worker radiation exposure.

Comment. One commenter asked if NRC considers powder a solid form.

Response. Yes, the NRC has always considered powder as a solid form when implementing § 71.63(a). However, powders, under the eliciting rule, were not considered as a solid form that was exempt from the double containment requirements of § 71.63(b).

Comment. One commenter endorsed NRC's proposal to retain the requirement that shipments whose contents exceed 20 curies of plutonium must be made in a solid form as provided under § 71.63(a).

Response. The comment is acknowledged.

Comment. One commenter expressed support for the NRC position.

Response. The comment is acknowledged.

Comment. ~~Two~~ **Several** commenters expressed concern that removing the double containment requirement would erode public confidence in the Waste Isolation Pilot Plant (WIPP) in southeastern New Mexico. One of the commenters noted that NRC's decision is not supported by any studies to demonstrate that the change is minimal and that NRC should only relax the double containment provisions when NRC receives scientific evidence that demonstrates beyond a reasonable doubt that single containment is as safe as double containment for shipments to WIPP. **Another commenter cited the economic, shipping, and public confidence aspects of a severe accident release as the primary arguments in support of retaining double containment.**

Response. The comments ~~is~~ **are** acknowledged. **With regard to the last commenter's citation, as is the case with other nuclides, NRC-certified Type B packagings provide for safety in transportation accidents. With regard to non-safety focused arguments (economic and public confidence issues), as well as the other commenter's concerns, also** the reader is referred to a related discussion earlier ~~in~~ **on** this issue, under the heading: Analysis of Public Comments on the Issues Paper.

Comment. One commenter discussed an incident involving the shipment of plutonium-containing transuranic waste to DOE's Waste Isolation Pilot Plant in New Mexico. A truck carrying TRU waste was involved in a traffic accident. While no radiation was released, the inner container was discovered to be contaminated with radiation to the extent that it could not be unloaded. The commenter pointed out that the double-walled container provided a margin of safety that would not have existed under the proposed rule. The commenter stated that the incident underscores the importance of maintaining the double containment requirement, as it has been a crucial element in the success of the WIPP TRU waste shipping campaign to date.

Response. In the cited case, NRC staff understands that neither containment was compromised due to the accident.

Comment. One commenter stated that all shipping requirement revisions should be more, rather than less, protective of public health. Two other commenters stated that the AEC's original 1974 reasoning for imposing the double containment requirements was still valid, including the possibility for human error and expected increases in the number of shipments. The commenter also responded to the claim that adopting a single containment requirement would be safer for personnel who handle the inner container by stating that this may simply be a shifting of risk from personnel to the public.

Response. The comment that shipping requirement revisions should all be more, rather than less, protective of public health, is acknowledged. The NRC's transportation regulations are designed to provide adequate protection to the public health and safety from radioactive material transportation activities. In doing so, NRC seeks to balance its regulations by ensuring public health and safety while at the same time not creating unnecessary regulatory burden.

Regarding the comment that the AEC's original 1974 reasoning for imposing double containment is still valid, the NRC notes that the AEC's original reasoning was based on the fact of transporting liquids; that is no longer the case. The justifications for elimination of the double containment requirement detailed in the proposed rule on April 30, 2002 (67 FR 21421 through 21425) is based on technical arguments and focus on the confidence in Type B packages. While there is an increase in the number of shipments to WIPP, the vast majority of these shipments do not involve liquids.

The NRC disagrees with the comment that while the adoption of a single containment requirement would be safer for personnel who handle the inner container, this constitutes a shifting of the risk from personnel to the public. The NRC believes that the risk of shipping plutonium in a single containment Type B package is no different than that of shipping other radionuclides with the same or lower A_1 and A_2 values than plutonium.

Comment. One commenter stated that although spent fuel that is damaged to the extent that the rod cladding's integrity is in question may be subject to the requirements of § 71.63, it is not clear that all damaged fuel will require double containment.

Response. NRC has previously published guidance (ISG-1, Rev. 1, dated October 25, 2002) on when the double containment provision is required for damaged spent fuel. Basically, canning (double containment) is required if the spent fuel contains known or suspected cladding defects greater than a pinhole leak or hairline crack that have the potential for release of significant amounts of fuel into the cask.

Comment. One commenter stated that additional procedures (e.g., closures and testing) are required to implement § 71.63, which leads to added worker exposures. The commenter provided quantitative and monetized data detailing the extra time and amount of money that the double containment requirement imposes on TRU Waste, Plutonium Oxides, and Damaged Spent Nuclear Fuel Operations.

Response. NRC acknowledges this comment.

Comment. One commenter stated that additional containment systems reduce cask capacities and consequently require more shipments to move the same material. This commenter also said that the double containment represents extra weight that must be moved and then provided estimates of the cost for moving the extra weight in the double-containment structure in the cases of TRU Waste, Plutonium Oxides, and Damaged Spent Nuclear Fuel operations.

Response. The comment is acknowledged.

Comment. One commenter stated that design costs and costs for NRC certification services are incurred by increased design complexity relating to the provision of the double-containment barrier. The commenter noted that the alternative to the design and certification cost penalty is to petition for an exemption under § 71.63(b)(4); however, preparing this petition is time-consuming and probably similar in cost to getting a separate containment boundary designed and certified. The commenter estimated certification and capital cost penalties for the cases of CH-TRU and RH-TRU Wastes, Plutonium Oxides, DHLW Glass Exemption, and Damaged Spent Nuclear Fuel.

Response. The comment is acknowledged.

Comment. One commenter stated that while the restrictions of § 71.63 remain in effect, it must continue to expend funds unnecessarily for double-containment packaging. This commenter provided tables of monetized breakdowns of these estimates. The commenter estimated that the net result from all three areas (TRU wastes, plutonium oxides and residues, and damaged spent nuclear fuel) is that double-containment requirements will produce an avoidable cost of approximately \$12 million in capital cost, \$20 million in operational cost, and \$26 million to \$40 million in shipping and receiving costs. In addition, the commenter estimated

that the double containment requirement will result in additional worker radiation exposure amounting to 1250 to 1770 person-rem.

Response. The commenter has provided information that appears to support the NRC's contention that removal of double containment would provide for cost savings and decreased personnel exposure.

Comment. One commenter stated that double containment provides some additional protection to the public in both normal and accident situations. The commenter stated that most of this additional protection relates to a potential reduction in population exposure. However, the commenter estimated that the total radiation exposure reduction in most cases amounts to a maximum of about 30 person-rem/year distributed among a potentially exposed population of tens of millions of persons. The commenter stated that such an effect would not be perceptible.

Response. NRC acknowledges the comment.

Comment. One commenter stated that, although double containment reduces the risk incurred by the public of exposure to radiation from the package in incident-free transport, the reduction is likely to be relatively small. The dose rate is already small enough at distances where the public is likely to be exposed that the impact of single- or double-contained material will not be consequential. This commenter also noted that one effective containment boundary is sufficient to meet containment requirements implicit in Type B design approvals, but the materials shipped are already within one or more inner containers. The commenter believes the presence of these redundant containers effectively rules out any problems that might result from human errors in achieving a required level of leak-tightness for single contained Type B packages.

Response. NRC acknowledges the comment.

Comment. One commenter stated that doubly contained packages pose lower risks and is not, by itself, sufficient justification for using doubly contained packages. The commenter stated that, in general, the likelihood of achieving an accident sufficient to compromise containment of a singly contained Type B package has been estimated to be fewer than 1 in 200 in the event of a severe accident. Achieving damage to two redundant containments could be expected to be as much as a factor of 10 lower risk relative to the single containment case. The commenter stated that this is not as large a benefit as it may seem; the decrease in absolute risk will be very small because the risk of shipping singly contained plutonium is exceedingly small to start. The commenter provided monetized and quantified estimates of the cost/risk tradeoffs associated with double-containment versus single-containment for the handling of Contact-Handled TRU Waste, Plutonium Oxide and Plutonium-Bearing Wastes, Remote-Handled TRU Waste, and Failed Fuel.

Response. NRC acknowledges the comment.

Comment. Two commenters stated that if the NRC continues to pursue the proposal to relax the plutonium shipment double containment standards, then it should conduct a series of hearings on the rulemaking, with at least one of those hearings held in the western U.S. Another commenter objected to the lack of public education regarding the "numerous, confusing, and complicated" proposed rule changes, which, when presented as they were, encourage nonengagement. The commenter requested that an extension be placed on the comment period and that "ordinary" language be used to explain the actual proposals, how they will impact public health, what agencies and rules are involved, and how one can easily reply to all agencies involved in these proposals by mail, email, or fax.

Response. The rulemaking process does not include the opportunity for formal hearings because the proposed rulemaking is not a licensing action, which does require hearings. The NRC staff thinks that the commenter meant holding public meetings to discuss

the issue. Hearings were held in this rulemaking in the form of public meetings. Two meetings were held in June 2002, in Chicago, IL, and the NRC TWFN Auditorium, and 3 meetings were held in NRC Headquarters, Atlanta, GA, and Oakland, CA, during August and September 2000. The NRC did not extend the 90-day public comment period, because the public had ample opportunity to comment on this rule during the 1-year period following March 2001, when the proposed rule was posted on the Secretary of the Commission website.

Responses to Comments from the Environmental Evaluation Group, April 8, 2004

Comment 1: Although the NRC has concluded there would be less radiation dose to workers if the double containment requirement was eliminated, there is no indication that the staff performed their own analyses or reviewed/observed time motion studies or looked at actual dose data for the one double contained package (TRUPACT-II) that dominates current shipping. Rather, the staff makes statements such as "agrees that removal of double containment would result in reduced risk to radiation workers"; "the NRC believes worker dose would be reduced"; and "elimination of the double containment requirement will likely result in a reduction in worker radiation exposure." EEG's detailed analysis concluded there would be less radiation exposure with double containment.

Response 1:

Although not the primary basis for the rule change, NRC considered the issue of whether elimination of the double containment requirement would serve to reduce risk to radiation workers. Commenters provided conflicting information on this issue. The NRC considered the information and expressed the view that worker doses would be decreased for single containment, due to less handling (for example, the single containment for future packages would have simpler loading procedures). NRC also noted that radiation protection of transport workers (e.g., drivers, inspectors) and the public is provided through the package maximum radiation levels set forth in the U.S. Department of Transportation (DOT) regulations, which do not depend on double containment.

Comment 2: The Federal Register amendment response to EEG's comments on the A_1/A_2 issue and the weight penalty from double containment was essentially that these issues are not important. Rather, the important point is that "the NRC believes the decision to eliminate double containment is risk informed and reduces an unnecessary regulatory burden." Also, "the primary reason for removing the double containment requirement is that the NRC has no technical justification or basis for maintaining double containment for plutonium or any other radionuclide." Yet, there is no discussion of why elimination of double containment is risk informed or any demonstration that the double containment requirement is a regulatory burden. It is EEG's position (which is developed more in EEG-89 than in the July 26, 2002 comments) that double containment has placed no practical burden on WIPP shipments because alternate single contained packages (TRUPACT-I, which was never certified and TRUPACT-III whose certification is pending), do not have advantages (relative to TRUPACT-II) in package weight, allowable payload, and waste volume capacity.

Response 2:

Requiring double containment for plutonium is not viewed as risk-informed because it is not consistent with the A_1/A_2 system for categorizing radionuclides for transport. As NRC explained in the final rule, "[t]here are many nuclides with A_2 values the same or lower than plutonium's for

which double containment has never been required. Thus, requiring double containment for plutonium alone is not consistent with the relative hazard rankings in Table A-1" (69 FR 3752). The Type B packaging standards, which the outer containment of plutonium shipments must meet, in and of themselves, provide reasonable assurance that public health and safety and the environment are protected during the transportation of radioactive material. Because the inner container is not needed, based on the A₁/A₂ system, it is an unnecessary regulatory burden on licensees. This regulatory burden consists of the cost of design, fabrication, and installation of the inner barrier itself, the loss of available payload due to existence of the inner container, and the additional exposure to workers from the additional handling needed for the inner container.

Comment 3: The Federal Register discussion states: "NRC continues to believe that a separate inner container provides an additional barrier to the release of plutonium in an accident (just as a package with triple containment would provide an even greater barrier to the release of plutonium in an accident). However, this type of approach is neither risk informed or performance based." The discussion offers no insight as to how the staff balanced whatever (theoretical) burden there might be to double containment versus the advantages of avoiding an accidental release that would have radiological contamination, shipping disruption, and public perception detriments in order to determine that double containment was not risk informed or performance based. Recently the NRC staff cites the transportation safety record of the last 30 years. Such complacency is reminiscent of old attitudes, which led Chairman Diaz recently to make the following statements regarding the Three Mile Island Accident: "Few experts thought that such a severe accident was even likely to happen... Confidence in the technology was very high."

Response 3:

NRC and DOT have undertaken significant efforts on these rules. The NRC based its decision on the excellent safety record of the NRC-certified Type B packages in which no fatalities or injuries have been attributed to material transported in a Type B package, the NRC certification process for these packages that include satisfying the 10 CFR Part 71 Hypothetical Accident Conditions, and the A₁/A₂ system, all of which underscore the fact that double containment is not needed to provide reasonable assurance of the health and safety of the public. The final 10 CFR Part 71 rule reflects the NRC's latest revision to its regulations to keep them compatible with International Atomic Energy Agency Safety Standards. The NRC periodically revises its regulations to reflect latest knowledge and experiences (69 FR 3698). We regret the impression that the removal of the double containment requirement may reduce public confidence. However, the Commission has the responsibility to both protect public health and safety and reduce unnecessary regulatory burden where possible. The NRC reviewed the petition that was submitted to eliminate double containment in the context of safety. In this review, we considered comments received from three publications in the Federal Register on this issue and six public meetings held across the country. The NRC staff also reviewed the available regulatory history for double containment. We believe the Commission has kept the public involved and informed of our actions on this rule and the reasons for our action.

Comment 4: The staff devotes a lot of attention to the requirement that liquid plutonium should not be shipped but downplays two other reasons for originally incorporating the double containment rule: (1) there would be a large number of shipments in the future; and (2) some waste will be shipped in respirable form. There will be over 20,000 future shipments to WIPP and much of this waste will contain respirable material.

Response 4:

Regarding the statement that some waste will be in respirable form, the A₁/A₂ system accounts for the potential of nuclides being in respirable form (69 FR 3720). The NRC's role in shipments to WIPP is limited to approving the design of packages used to transport the radioactive material to that facility, and is independent of the number of shipments. The NRC has concluded that the requirements in the revised 10 CFR Part 71 provide reasonable assurance for shipping container design, and from a risk informed perspective it should be recognized that the single containment design will reduce the amount of handling required during the shipment.

Comment 5: EEG's last major concern involves the threat of terrorist activity. We believe there is a greater likelihood of a radionuclide release from a terrorist attack on a single contained package. The removal of a barrier against release at this time of increased terrorist threat appears to be undesirable and inconsistent with the many nuclear security enhancements the NRC has made since September 11, 2001.

Response 5:

We share your interest in ensuring radioactive material security while in transport. Since September 11, 2001, the Commission has issued several security advisories; security orders (security orders contain requirements for licensees to implement additional security measures beyond that currently required by NRC regulations and as conditions of licenses); and associated guidance documents to the NRC licensees transporting certain radioactive materials. These guidance documents and additional security requirements have been tailored to the specific material being shipped and the risks associated with that material. Additionally, the NRC has performed vulnerability assessments on transportation packages for certain types of radioactive materials. We are also aware that the U.S. Department of Energy (DOE) has performed its own assessments of the risks associated with transportation of radioactive materials. With respect to shipments to the Waste Isolation Pilot Plant (WIPP), DOE is responsible for assuring or providing the security associated with such shipments, including potential sabotage. The NRC's role in shipments to WIPP is to approve, after they are found to be safe, the designs of packages used to transport the radioactive material to that facility. It should be noted that there are many actions, of a classified nature, that contribute to providing an appropriate level of security.